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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/598,396	08/25/2006	**Erika Hoffmann**	JCLA21561	3602

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EXAMINER	
HEYER, DENNIS	
ART UNIT	PAPER NUMBER
4121	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/598,396	HOFFMANN, ERIKA	
	Examiner	Art Unit	
	DENNIS HEYER	4121	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *32-70* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *32-70* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to **elect a single invention** to which the claims must be restricted.

Group I claims 32– 49, 56 – 59 and 65 – 70 drawn to a medical product

Group II claims 50 – 55, 61 – 64 drawn to a method for coating a medical product

As set forth in Rule 13.1 of the Patent Cooperation Treaty (PCT), "the international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept." Moreover, as stated in PCT Rule 13.2, "where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features." Furthermore, Rule 13.2 defines "special technical features" as "those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art."

The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical feature of Group II, a method for preparation of a biocompatible coating of a medical product is anticipated by the prior art. As disclosed in Goldberg *et al.* (US patent 6,387,379) this reference teaches a solid support (i.e. surface) which has been modified for contact with human tissue. The method comprising an ethylenically unsaturated monomer (Abstract) with at least on alkyl moiety (Claim 15) and at least one biofunctional active agent, which may be antiinflammatory (Claim 16). The monomer may be polymerized by exposure to light (irradiation) to provide a surface in which the active agent is physically trapped. Thus the elements of the subject matter relating to Claims 50 and 51 of Group II of the instant application are not novel over the prior art.

As such, Group II does not share a special technical feature with the instant claims of Groups I – II. Therefore, the claims are not so linked within the meaning of PCT Rule 13.2 so as to form a single inventive concept, and unity between Groups I and II is broken.

Election of Species

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

If Group I is elected, EACH of the following species elections, a, b and c, is required:

a) Regarding Claim 32: Elect a **single specific compound or** a **single mixture of compounds** from the substances containing at least one alkyl group with at least one multiple bond as described in Claim 32, as disclosed on pages 5 – 12 in the instant specification or otherwise disclosed; with claims 32 – 38 reading on this species. Claims 32, 39 – 49, 56 – 60 and 65 – 70 are generic.

b) Regarding Claim 40: Elect a **single specific compound or** a **single mixture of compounds** from the substances not participating in the polymerization reaction as described in Claim 40 or otherwise disclosed in the instant specification; with claims 40 – 44 reading on this species. Claims 32 – 39, 45 – 49, 56 – 60 and 65 – 70 are generic.

c) Regarding Claim 45: **I** Indicate **whether or not** an antiproliferative, antiinflammatoric and/or antithrombotic active agent as listed in Claim 45, is present on the surface of the medical product according to Claim 32. **If present**, elect a **single active agent compound or specific mixture of compounds** as disclosed in Claim 45

or otherwise disclosed; with claims 45 – 48. Claims 32 – 44, 47 – 49, 56 – 60 and 65 – 70 are generic.

If Group II is elected, EACH of the following species elections a, b, c and d, is required:

a) Regarding Claims 50 and 51: Elect a single method for preparing the biocompatible coating: **either** the method of Claim 50 **or** the method of Claim 51. If Claim 50 is elected, claims 52 – 56, are generic. If Claim 51 is elected, claims 57 and 59 – 60, are generic

b) Regarding Claims 50 and 51: Elect a **single specific compound or** a **single mixture of compounds** from the substances containing at least one alkyl group with at least on multiple bond as described in Claim 32 or, as disclosed on pages 5 – 12 in the instant specification or, otherwise disclosed; with claims 50 and 51 reading on this species. Claims 50 – 55 and 61 – 64 are generic

c) Regarding Claims 51 and 52: Indicate **whether or not** the method for preparing the surface of the medical product comprises deposition and/or incorporation of an antiproliferative, antiinflammatoric and/or antithrombotic active agent as described in Claim 51 and 52. **If** said deposition step is **present**, elect a **single active agent compound or specific mixture of compounds** as disclosed in the instant specification; with claims 51 – 52, 54 – 55, 61 and 63 – 64, reading on this species. Claims 50 and 56, are generic.

d) Regarding Claims 53 and 62: Indicate **whether or not** the method for preparing the surface of the medical product according to Claim 50 or 51, comprises, step "e", deposition of another polymerized layer as described in Claims 53 and 62. **If** said polymerized layer is **present**, elect a **single polymer compound or specific mixture of polymer compounds**, as described in Claim 53 and 62, or otherwise disclosed, with claims 51 – 52 and 54 – 55, reading on this species. Claims 50 – 52, 54 – 55, 61 and 63 – 64 are generic.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features in that each species contains a distinct moiety such that species is of a dissimilar nature for reasons discussed supra.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP

§ 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DENNIS HEYER whose telephone number is (571)270-7677. The examiner can normally be reached on Monday-Friday 8AM-5PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patrick Nolan can be reached on (571)272-0847. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DH

/Patrick J. Nolan/
Supervisory Patent Examiner, Art Unit 4121